REMARKS

Withdrawn Claims 36-56 and claims 56-69

Claims 36-56 are again withdrawn from consideration. In the Office Action of June 19, 2003, it is argued that the prior request for reconsideration of the withdrawn status of these claims is denied because the claims are not dependent on claim 14. This, however, is no justification for withdrawing these claims from consideration.

Dependency does not determine whether claims are drawn to the same invention. This rationale is akin to arguing that one can only have one independent claim in an application. If there are two independent claims then there is be at least one claim which has a different dependency lineage.

The facts show clearly that the subject matter of claims 36-56 are drawn to the same general subject matter as the examined claims. **Independent claims 36, 37, 38, and 56 are all directed to methods of contraception in a female mammal. The same is true for examined independent claim 14. Claims 36, 37, 38, and 56 all recite, during a period of at least 28 days (e.g., 28-84 days), administering a gestagen and during the last 5-10 days of that period administering a gestagen and a natural estrogen. The same is true for examined independent claim 14.** The Examiner has presented no rationale as to why these claims reciting these similar features are directed to different inventions.

The subject matter of claims 36, 37, 38, 56, and the claims dependent thereon is undeniably related to the subject matter being examined. There is nothing of record to support the allegation that a separate search is required. There is nothing of record to support that there is any serious burden imposed on the Examiner in examining these claims with the elected subject matter.

As for claims 56-69, these claims were withdrawn from consideration in the most recent Office Action without any explanation. It is noted that several of these claims, namely 57, 62, and 67-69, depend directly from claim 14. New claims 70 - 77 also depend, directly or indirectly, from claim 14.

Withdrawal of the holding of claims 36-69 as being withdrawn from consideration is respectfully requested. Conversely, if the Examiner maintains this rejection, applicants request that the Examiner articulate the particular rationale for withdrawing these claims from

consideration and to make that determination final so that applicants can proceed with a petition.

Amendments

New claims 70-77 are directed to further aspect of applicants' invention. These claims are supported throughout the disclosure. See, e.g., the Examples and the original claims. Claims 8-12 and 31-35 are cancelled.

Rejection under 35 USC § 112, second paragraph

Claims 3-7 and 14-30 are rejected as allegedly being indefinite. This rejection is respectfully requested.

The meaning of the term "comprising" in claims is clear. The fact that this transition phrase, which is extremely commonplace in US patents, is open-ended does not in any manner makes its meaning indefinite. Even the Board in *Ex parte Davis et al.*, 80 USPQ 448 (POBA 1948) [cited by the Examiner] state that the meaning of "comprising" was well settled by numerous decisions. The Board in *Davis* did not hold that "comprising" was indefinite. Similarly, the Board in *Ex parte Gottzein et al.,* 168 USPQ 176 (POBA 1970) also did not hold that "comprising" was indefinite.

In the rejection, it is argued that the last clause in claim 14 does not have specific dates and that "at least" is too open-ended. Again, these assertions do not demonstrate that the claim is indefinite. One of ordinary skill in the art can readily determine whether a given treatment method has a period in accordance with the period described in applicants' claims. One simply looks at the overall period and the individual phases of the given treatment regime to see if they are in accordance with the period and phases recited in applicants' claims.

Breadth is not indefiniteness. See, e.g., *In re Gardner et al.,* 166 USPQ 138 (CCPA 1970). Further, it is noted that applicants added dependent claims that recited specific day ranges for the period recited in claim 14, but the Examiner held these claims to be withdrawn (i.e., claims 67-69).

In view of the above remarks, it is respectfully submitted that one of ordinary skill in the art can readily recognize whether a given method fall within or outside the literal scope of applicants' claims. Nothing more is required under the statute. Withdrawal of the rejection is respectfully requested.

Rejection under 35 USC § 112, first paragraph

Claim 3-7 and 14-30 are again rejected under 35 U.S.C. § 112, first paragraph on grounds of alleged lack of enablement. This rejection is respectfully traversed.

In the rejection, it is stated that various combination of gestagens and estrogens using different dosage regimes are known within the art. This is correct and is evidence of the well developed nature of the art and the large amount of past and ongoing research. Such a developed art facilitates routine experimentation.

It is noted that the prior art of record refer to gestagens and estrogens generally. See, for example, the claims of Gast, Konnincx, Hodgen, and Jager. In each of these references, the claims refer both to estrogens and gestagens in general. Thus, using the terms estrogens and gestagens broadly is conventional in this field and demonstrates recognition within the art that the use of such general concepts is sufficient.

The allegation that the pharmaceutical art is generally unpredictable does not lead to a conclusion of undue experimentation. Applicants' specification does provide examples of specific gestagens, natural estrogens, periods, phases, and amounts. With such information, one of ordinary skill in this art can readily practice the invention using no more than routine experimentation.

Contrary to the allegation in the rejection, one of ordinary skill in the art would not "be at a loss as to where to begin." Applicants' specification, as mentioned above, provides more than adequate information such as examples of specific gestagens, natural estrogens, periods, phases, and amounts, to practice the invention using no more than routine experimentation. Applicants' specification provides examples of gestagens and estrogens for use in the claimed method as well as suitable administration dosages. In addition, in Applicants' examples 1-8 specific method embodiments are described. Thus, the assertion that "no guidance" is provided is clearly wrong. Based on the information in the disclosure and the large amount of information available within this particularly well developed art, one of ordinary skill in the art can practice the claimed invention without undue experimentation.

In the rejection, it is alleged that the claims are broad and the specification does not include any *in vivo* or *in vitro* test data. However, it is respectfully submitted that the claims are not broad, especially in light of the state of the art, nor is it required that *in vivo* or *in vitro* test

data be presented in the specification.

As mentioned above, the field of oral contraceptives is a well developed field. One of ordinary skill in this relevant art is well aware of procedures used for both *in vivo* or *in vitro* testing of oral contraceptive preparations. See, for example, Hodgen (U.S. 5,898,032) regarding *in vivo* studies using monkeys. Moreover, such examples are not needed to objectively enable one of ordinary skill in the art. See, for example, the disclosures of Konnicx, Gast and Jager, all of which disclose oral contraceptives using particular dosage regimens but do not present any *in vivo* or *in vitro* tests. By now it is well settled law that one of ordinary skill in the art need not disclose that which is well known in the art. See, e.g, *Hybritech Inc. v. Monoclonal Antibodies, Inc.,* 231 USPQ 81 (Fed. Cir. 1986).

Thus, in vitro and in vivo test models are well known within this art. Determining the relative efficacy of any particular combination of gestagen and natural estrogen requires no more than routine experimientation.

All that is required under the statue is objective enablement. It is not required that applicants' disclosure presents in vivo or in vitro test results. See, e.g., *In re Marzocchi et al.*, 169 USPQ 367, 369(CCPA 1971):

> The first paragraph of §112 requires nothing more than objective enablement. How such a teaching is set forth, either by the use of illustrative examples or by broad terminology, is of no importance.

An application disclosure which contains a teaching of the manner and process of making and using an invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken in compliance with the enabling requirement of the first paragraph 35 U.S.C. § 112 unless there is reason to doubt the objective truth of statements contained therein relied on for enabling support. *In re Brana, 51 F.3d 1560,* 34 USPQ2d 1436 (Fed. Cir. 1995). *Fiers v. Revel, 984 F.2d 1164,* 24 USPQ2d 1601 (Fed. Cir. 1993). Furthermore, as stated in *In re Marzocchi*, 169 U.S.P.Q. 367, 369 (CCPA 1971), the PTO must have adequate support for its challenge to the credibility of applicant's statements of utility. See also *In re Bundy*, 209 USPQ 48 (CPA 1981).

Also, it is by now well settled law that the test for enablement is not whether any

experimentation is needed but whether or not that experimentation is undue. See, *In re Angstadt*, 190 USPQ 214, 219 (CCPA 1976) in which the art involved (catalysis) was acknowledged to be unpredictable. Even a considerable amount of experimentation, or complex experimentation, is permissible if it is routine. See, e.g., *Ex parte Jackson,* 217 USPQ 804, 807 (POBA 1982) and *In re Wands*, 8 USPQ 2d 1400, 1404 (Fed. Cir. 1988)

In view of the above remarks, it is respectfully submitted that Applicants' disclosure provides more than sufficient guidance to objectively enable one of ordinary skill in the art to make and use the claimed invention with no more than routine experimentation. Withdrawal of the rejection under 35 U.S.C. §112, first paragraph, is respectfully requested.

Rejection(s) Under 35 USC § 103 in view of Weiner et al.

Claims 3-7 and 14-30 are again rejected as being obvious in view Weiner at al. This rejection is respectfully traversed.

Weiner et al. disclose a treatment for contraception in which three silastic rods impregnated with 40 mg d-norgestrel are implanted in to the forearms of four patients are left in place for 100-458 days. After about 300 days of treatment, the patients were given a daily oral dose of 50 μg of ethynylestradiol, a synthetic steroid (see attached excerpt form The Merck Index, 11th Edition (1989)), for 21 days. Weiner et al. disclose that its synthetic estrogen increases the concentration of sex hormone binding globulin in plasma. Weiner et al. does not disclose that the dosage regime provides cycle control and regular menstrual bleeding.

In the Office Action, it is argued that it "does not matter that the prior art uses a synthetic steroid because it teaches the same *method* as the presently claimed invention." This statement is at best confusing. First, it does matter. The prior art uses a synthetic estrogen and applicants' method uses a natural estrogen. The prior art provides no suggestion or motivation to use a natural estrogen in its method. Further, the rejection makes no assertion of any motivation for so modifying the prior art. Motivation is a requisite showing for an obviousness rejection. Merely asserting, without rationale, explanation or support, that motivation is provided by the prior art does not establish that motivation exists. Second, the prior art does not disclose the same method. For example, it uses a synthetic estrogen, not a natural estrogen.

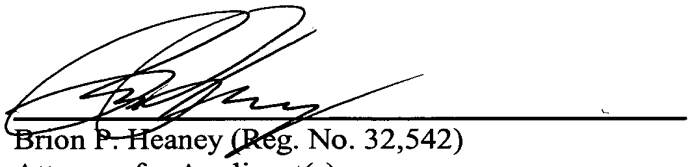
Weiner et al. provide no suggestion of using other combinations of estrogens and gestagens. No other agents other than d-norgestrel and ethynylestradiol are mentioned. The

mere ability to modify a disclosure does not by itself establish obviousness. Instead, there most be some motivation established to modify the prior art. See, e.g., *In re Gordon,* 221 USPQ 1125, 1127 (Fed. Cir. 1984) and *In re Laskowski*, 10 USPQ 2d 1397, 1398 (Fed. Cir 1989). In the instant case, no such motivation is presented.

Weiner et al. fails to provide any motivation that lead one of ordinary skill in the art to modify the disclosed method to achieve a method having a dosage regimen (combination and dosage schedule) in accordance with the claimed invention. An assertion of obviousness is determined from the vantage point of a hypothetical person having ordinary skill in the art to which the patent pertains. To assess this determination, the hypothetical person has the relevant prior art in from of him, but has **no knowledge of applicants' invention**. Motivation is not established simply by assuming that the prior art can be modified. It is more than this. The establishment of motivation requires a rationale as to why one would be directed toward making particular modifications.

For the reasons discussed above, withdrawal of the prior art rejection and allowance of the application are respectfully requested.

Respectfully submitted,



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